



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,303	01/20/2004	Barry Lenard Reed	025217-0122	7169
22428	7590	07/28/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				GEORGE, KONATA M
ART UNIT		PAPER NUMBER		
		1616		

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,303	REED ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 January 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/4/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 36-55 are pending in this application.

Disposition of Previous Office Action

1. The office action mailed November 16, 2005, will be vacated as the wrong claimed were examined.

Drawings

2. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on May 4, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Terminal Disclaimer

4. Examiner acknowledges the filing of a terminal disclaimer against the following applications/patents: 09/910,780 (US 6,818,226); 09/125,436 (US 6,299,900); 10/428,012 (US 6,916,486); 10/428,016 (US 6,929,801); 10/428,017; 10/428,018 (US 6,923,983) and 10/428,019 (US 6,916,487).

Claim Objections

5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 36-54 been renumbered 36-55. Applicant has two claims numbered 44.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (US 5,100,918) in view of Knight et al. (US 6,165,453,306,2520).

Applicants claims an apparatus for applying a physiologically active agent to the dermal surface comprising a container and in said container an non-occlusive percutaneous or non-occlusive transdermal drug delivery system that comprises a therapeutically effective physiologically active agent, a dermal penetration enhancer and a volatile liquid to act as a vehicle.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Sunshine et al. teach in column 10, lines 33-40 a topical composition comprising S(+) ibuprofen in an amount sufficient to prevent or treat ultraviolet radiation-induced erythema (0.5 to 10 wt%). The composition can contain suitable solvents or vehicles including ethanol, etc. (col. 9, lines 35-38). The topical composition can be combined with other types of sun-protective and/or anti-erythema topical agents such as sunscreens containing PABA ester (col. 10, line 49 through col. 11, line 10). Column 10, lines 1-20 teach topical ingredients that are present in commercial sunscreens such as preservatives and oils.

Knight et al. discloses a shielded aerosol medicament dispenser for applying a medicament to a specific part of the body. The device comprises a vessel having a pressure chamber containing the fluid under pressure, a valve member and a hood mounted in a fixed axial position (col. 1, lines 36-52). It can be concluded from figure 1,

that the nozzle of the device is placed perpendicular to the dermal surface. Examiner interprets the hood of Knight to be equivalent to the shroud of the instant invention.

Applicants' describes the shroud on page 45, [0227] to "...envelope[s] the spray, providing an effective closed system which deposits the active agent into the skin...".

The hood portion of the device of Knight delivers the active agent in the same manner as claimed by applicant (see Fig. 1).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Sunshine et al. does not teach a container for the composition or that the delivery system provides metered doses and contains a shroud.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Knight et al. (devices for the delivery of the composition an aerosol medicament dispenser) with the composition of Sunshine et al. (composition comprising an active agent and a sunscreen) to teach the claimed invention of a container comprising an active agent and a sunscreen and a container for the composition. With respect to the system providing meter doses, it is the position of the examiner that when the pumps of the aerosol and non-aerosol devices are depressed, the device delivers a metered dose of the composition to the patient.

Conclusion

7. Claims 36-55 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) as 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Technology Center 1600



Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600